

MIND-BODY INTERACTIONS AND HEALTH: EXPLORATORY/DEVELOPMENTAL RESEARCH
PROGRAM (R21)

RELEASE DATE: January 9, 2003

RFA: OB-03-005

Office of Behavioral and Social Sciences Research (OBSSR)

(<http://obssr.od.nih.gov>)

Fogarty International Center (FIC)

(<http://www.fic.nih.gov>)

National Cancer Institute (NCI)

(<http://www.nci.nih.gov>)

National Center for Complementary and Alternative Medicine (NCCAM)

(<http://nccam.nih.gov>)

National Eye Institute (NEI)

(<http://www.nei.nih.gov>)

National Heart, Lung, and Blood Institute (NHLBI)

(<http://www.nhlbi.nih.gov>)

National Institute of Alcohol Abuse and Alcoholism (NIAAA)

(<http://www.niaaa.nih.gov>)

National Institute of Allergy and Infectious Diseases (NIAID)

(<http://www.niaid.nih.gov>)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

(<http://www.niams.nih.gov/>)

National Institute of Child Health and Human Development (NICHD)

(<http://www.nichd.nih.gov>)

National Institute of Dental and Craniofacial Research (NIDCR)

(<http://www.nidr.nih.gov>)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

(<http://www.niddk.nih.gov>)

National Institute of Mental Health (NIMH)

(<http://www.nimh.nih.gov>)

National Institute of Neurological Disorders and Stroke (NINDS)

(<http://www.ninds.nih.gov>)

National Institute on Aging (NIA)

(<http://www.nia.nih.gov>)

National Institute on Drug Abuse (NIDA)

(<http://www.nida.nih.gov>)

LETTER OF INTENT RECEIPT DATE: June 16, 2003

APPLICATION RECEIPT DATE: July 16, 2003

THIS RFA CONTAINS THE FOLLOWING INFORMATION

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PURPOSE OF THIS RFA

The National Institutes of Health (NIH), through the participating Institutes, Centers, and Offices listed above, invite applications for infrastructure grants in support of research on mind-body interactions and health. "Mind-body interactions and health" refers to the relationships among cognitions, emotions, personality, social relationships, and health. Applicant institutions may request funds to support infrastructure and research designed to (1) enhance the quality and quantity of mind-body and health research and (2) develop new research capabilities to advance mind-body and health research through innovative approaches. These activities must reflect a research theme that is driven by scientific questions within the context of "Mind-body interactions and health" research. A central goal of this program is to facilitate interdisciplinary collaboration and innovation in mind-body and health research while providing essential and cost-effective core

services in support of the development, conduct, and translation into practice of mind-body and health research based in centers or comparable administrative units.

This announcement invites applications for R21 EXPLORATORY/DEVELOPMENTAL AWARDS. Exploratory/Developmental Awards are intended to support the development and demonstrate the feasibility of programs at institutions that have high potential for advancing mind-body and health research, but have not yet fully achieved the necessary resources and mechanisms to qualify for a R24 Research Infrastructure Award. (See [RFA-OB-03-004](#), Mind-Body Interactions and Health: Research Infrastructure Program.)

RESEARCH OBJECTIVES

Background

The Public Health Service has documented that many of the leading causes of morbidity and mortality in the U.S. are attributable to social, behavioral, and lifestyle factors (e.g., tobacco use, lack of exercise, poor diet, and drug and alcohol abuse). Numerous studies have also documented that psychological stress is linked to a variety of health outcomes, and researchers and public health officials are becoming increasingly interested in understanding the nature of this relationship. Research has shown, for example, that psychological stress can contribute to increased heart disease and decreased immune system functioning. Other research has demonstrated that cognitions (attitudes, beliefs, values), social support, prayer, and meditation can reduce psychological stress and contribute to positive health outcomes. Consequently, over the past decade the National Institutes of Health have increased efforts to encourage and support health and behavior research (e.g., RFA on Innovative Approaches to Disease Prevention Through Behavior Change, NIH Guide to Grants and Contracts, Volume 26, Number 36, October 24, 1997). Mind-body research is viewed as one component of health and behavior research. In 1999, using funds especially appropriated by Congress to the OBSSR, the NIH issued a Request for Applications (RFA) for Centers for Mind-Body Interactions and Health (OD-99-005) and subsequently awarded five P50 Center Grants (http://obssr.od.nih.gov/RFA_PAs/MindBody/mbpage.htm).

More recently, the NIH has commissioned a series of reports from the National Research Council and the Institute of Medicine, such as "New Horizons in Health: An Integrative Approach" (National Academy Press, 2001) and "Health and Behavior: The Interplay of Biological, Behavioral, and Societal Influences (National Academy Press, 2001). These reports include calls

for expansion of interdisciplinary health research on mind-body topics. (See summary of recommendations at <http://obssr.od.nih.gov/Publications/NRC-Reports.htm>.)

Objectives and Scope

The primary purposes of the Mind-body and Health Exploratory/Developmental Research Program are to provide resources to support and advance research that will improve the understanding of mind-body interactions and health, facilitate interdisciplinary collaboration among investigators conducting health-related mind-body research, and promote innovative approaches to mind-body and health research questions. An additional goal is to facilitate interaction among scientists in locations throughout the United States in order to contribute to the integration and coordination of mind-body and health research.

The EXPLORATORY/DEVELOPMENTAL AWARD (R21) is intended to support the improvement of research units that have high potential for advancing mind-body and health research. The award provides such units the opportunity to further develop the mechanisms and resources required to support and facilitate significant new contributions to the field and to build a substantial interdisciplinary portfolio of mind-body and health research.

Applicant institutions responding to this RFA must articulate a coherent, integrated, and interdisciplinary conceptual or substantive research theme (e.g., an organizing set of questions and issues) that underlies their activities and efforts to advance understanding of the mechanisms involved in "Mind-body interactions and Health". The central scientific objectives and themes of the unit must be relevant to the NIH mission. Illustrative examples of mind-body and health research topics that fall within the mission are listed below. Applicant institutions are encouraged to consult with program staff listed under INQUIRIES to determine the relevance of other topics to the NIH mission.

Research Topics

Three areas of research are emphasized. In addition, special importance is given to mind-body research in diverse racial/ethnic and socioeconomic status populations (e.g., cultural beliefs regarding health; perceived racism and health; distrust of health care systems and health care utilization). The formation of multidisciplinary teams to perform the research of this initiative is viewed as essential.

1. The first area of emphasis is the effect of cognitions or personality (e.g., beliefs, attitudes, and values; modes of thinking) and of emotions on physical health. Included is research on social, psychological, behavioral, affective, and biological factors mediating these effects. What are the physiological, behavioral, and social pathways by which beliefs, attitudes, and values or particular stress-management interventions affect health? How do emotions, personality, and cognitions interact to affect health?

2. The second emphasis is on determinants or antecedents of health-related cognitions (beliefs, attitudes, or values; modes of thinking; decision-making styles). That is, given that some beliefs and attitudes have been shown to affect health, how are these beliefs, attitudes, and values developed, maintained, or changed?

Specifically, this RFA will support research that addresses issues such as: What contributes to individual differences in the beliefs, attitudes, and values that affect health and biological processes? How are health-related beliefs, attitudes, and values formed, maintained, and changed? How do social class, family, culture, disability, age, gender, or ethnicity influence health-related beliefs, attitudes, values, or cognitive styles?

3. The third is on how stress influences physical health, including: (a) basic research investigating how affect, attitudes, beliefs, and values influence perceived stress, individual differences in the biology of stress, and interactions between stress and behavioral risk factors for disease; (b) behavioral, affective, and biological mediators of the relationship between stress and health or disease, (c) the evaluation of mind-body interventions (e.g., relaxation-based, cognitive therapy, or support group) for physical illness and/or biological functioning, and (d) the translation of successful interventions into programs deliverable in clinical settings. These interventions may be examined alone or in conjunction with other stress management techniques.

Issues such as the following would be appropriate here: Through which psychological or physiological pathways do stress management approaches affect health? What are the effective components in successful stress-management practices? Does the combination of various stress management techniques improve outcome? Are particular stress-management interventions more effective for certain individuals, populations, or health outcomes? Can successful stress-management practices be effectively implemented in natural settings? What are the possible economic implications of utilizing stress management interventions? What are the factors that lead to individual differences in how stress is experienced and managed as well as in the health consequences of stress?

Examples of topics of interest specific to the Institutes that have joined with OBSSR in supporting this initiative are:

o FORGARTY INTERNATIONAL CENTER

The Fogarty International Center (FIC) is particularly interested in Mind-Body programs that draw upon, enhance, or expand existing FIC-funded biomedical and behavioral research collaborations between U.S. scientists and scientists in low- to middle-income countries that address global health issues. For example, research exploring the impact of attitudes and values on Tobacco use initiation and cessation in developing countries, the effects of beliefs and stress associated with Stigma on health outcomes, and the potential influence of attitudes and behaviors on susceptibility and response to treatment for HIV/AIDS and other infectious diseases might complement and synergize with existing FIC programs. In addition, many developing countries have populations with considerable experience in the use of mind-body interaction techniques in their traditional medicines and this may be one avenue to explore within larger collaborative research programs. Any area of research within existing FIC programs that can meaningfully incorporate mind-body issues would be of interest (see FIC website). FIC will not make independent awards, but will work in partnership with other NIH components on this program.

o NATIONAL CANCER INSTITUTE

The National Cancer Institute is particularly interested in stimulating research that examines interactions among environmental factors, psychosocial variables, immune, neuroendocrine, genetic, and other potential biological mediators and disease related outcomes. Such research may span the cancer control continuum, from prevention to survivorship, and may include a focus on such relevant topics as host individual differences, "sickness behaviors" (e.g., nausea, fatigue), and biological factors impacting tumor growth or metastasis beyond immune surveillance (e.g, DNA damage and repair, apoptosis, angiogenesis). Special emphasis is placed on interdisciplinary research and integrative conceptual models.

o NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Mind-body interventions represent one of the major domains of complementary and alternative medicine (CAM). This domain includes CAM practices that intend to facilitate the mind's capacity to affect bodily functions and lessen symptoms of disease. These diverse practices are of interest to NCCAM and include, but are not limited to, various types of meditation; unconventional uses of hypnosis; prayer and other forms of mental healing; and art therapy. In addition, many traditional medical systems, such as Traditional Chinese and Ayurvedic Medicine utilize mind-body CAM techniques. NCCAM is also interested in research on the placebo effect and studies on practitioner-patient interactions. Specifically related to this RFA, NCCAM is interested in

research involving the types of mind-body interventions described above that can help elucidate how personality, cognitions, emotions, as well as beliefs and attitudes, can effect physical health; and how and whether CAM mind-body interventions can enhance healing and reduce the physical manifestations of illness. In addition, certain mind-body interventions, including cognitive-behavioral therapies and various means of stress reduction, which are being adopted in some settings by mainstream medicine, continue to be of interest to NCCAM. NCCAM encourages CAM-related mind-body research that draws upon contemporary tools of neurobiology, neuroimmunology, and neuroendocrinology using state-of-the-art imaging, cellular, biochemical and molecular approaches.

o NATIONAL EYE INSTITUTE

The NEI is interested in supporting research that aims to investigate the relationship between psychosocial factors and their relationship to visual disorders. Most of the significant causes of blindness and visual impairment are associated with aging, and age-related macular degeneration (AMD) and diabetic retinopathy are major causes of severe vision loss in the elderly. Decreased vision in the elderly and others affects their quality of life and their ability to perform normal activities of daily living, such as driving, reading, and interacting socially. The dissemination and use of visual health information and visual impairment rehabilitation are crosscutting areas of emphasis in visual health that are impacted by social, psychological and behavioral domains. Beliefs and values critically influence the use of vision care services in at-risk populations. Research has shown that in some at-risk populations, knowledge and access to dilated eye examinations as an effective means of detecting treatable retinopathy nonetheless do not get regular dilated eye examinations. Underlying social, behavioral and psychological factors also influence compliance in the use of assistive devices, environmental modifications and rehabilitation strategies by visually impaired persons. Areas of research that address these and other topics which meaningfully incorporate mind-body issues relevant to visual health would be considered responsive to this announcement.

o NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The NHLBI supports behavioral research designed to investigate the relationship between psychosocial factors (e.g., depression, social support, stress, emotions) and diseases and disorders of the circulation, respiratory system, and blood, or sleep disorders. Other areas include the cognitive, emotional, motivational and other processes involved in risk assessment, decision-making and formation, change, or maintenance of health habits. Of particular interest are interactions between any of the above and the social environment, and translation of basic behavioral research to clinical applications. Finally, study of the interaction between psychosocial factors and genetic endowment is encouraged. The Institute supports a wide range of research

on the etiology, pathophysiology, treatment, and prevention of these disorders, and welcomes integrative, multidisciplinary behavioral research in any of these areas.

o NATIONAL INSTITUTE OF ALCOHOL ABUSE AND ALCOHOLISM

The NIAAA is particularly interested in the mind-body interaction as it enhances our understanding of alcohol abuse and alcoholism and the way this interaction impacts the prevalence and incidence of alcohol abuse and alcoholism. Studies of mind-body interactions may include, but not be limited to, research on the influence of spirituality, stress, and cognitive-behavioral factors on the development and maintenance of drinking behavior, treatment of alcohol disorders, and relapse. While the role of spirituality in achieving and maintaining sobriety is widely acknowledged, research is needed to determine the underlying mechanisms involved and thereby suggest new therapeutic strategies to optimize treatment and enhance relapse prevention. We need to understand how mind-body interactions may influence risk and resilience factors, e.g., stress and self-reliance. The mind-body interaction may influence the intervention process, particularly cognitive-behavioral techniques. It is anticipated that such knowledge could be incorporated into more effective means of preventing and treating alcohol disorders among adolescents as well as adult populations. Additionally, the NIAAA is committed to reducing alcohol-related health disparities in vulnerable populations. The mind-body interaction may enhance understanding of how reactions to stress, stigma, racism, and discrimination may influence the incidence to alcohol abuse and alcoholism.

o NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NIAID is interested in research that will further our understanding of the mind-body interrelationships as they relate to the susceptibility of an individual to infectious diseases such as HIV-AIDS and malaria, or the development of chronic diseases such as tuberculosis, hepatitis, pneumonia, and sinusitis. Examples of topics of interest include: the role of stress on reactivation of latent intracellular pathogens and susceptibility or resistance to infectious diseases, characterization of the effects of stress on microbial pathogenesis within the context of co-infections or nutritional status, identification of molecules regulating immune-nervous system interactions, the effects of stress on innate and adaptive immunity including the effects on the secretion of inflammatory mediators and the redistribution of immunocompetent lymphocytes, and the impact of immune deficiency on function of the nervous system. It is anticipated that these studies will be designed on the basis of sound scientific arguments with clearly defined outcome measures such as cytokine profiles, functional assays for humoral or cell mediated immune responses, and assessment of intracellular signaling molecules. The use of novel approaches, recent technologies in genomics, proteomics, immunology and molecular biology as well as the creation of collaborative scientific teams are particularly encouraged.

o NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

The NIAMS is interested in mind-body research relevant to arthritis and other rheumatic diseases, muscle diseases, musculoskeletal disorders, bone diseases including osteoporosis, and skin diseases. Research on stress-related alterations in physiological function with potential health consequences in autoimmune diseases (e.g., stress and flares in systemic lupus erythematosus or rheumatoid arthritis) and evaluation of mind-body interventions in diseases within the NIAMS mission are especially of interest.

o NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

The NICHD is particularly interested in interdisciplinary research projects examining mind/body interactions that influence child health and development. Studies are encouraged that: examine the interrelationship of socio-economic status and/or poverty with child health and development; examine the interrelation of mind/body interactions as explanations of health disparities in children and young adults; examine psychological stress and pain in children and adolescents and their effects on the immune system and illness; examine the influence of religiosity and spiritualism on risk behaviors and health in children and adolescents; examine the use of complementary medicines in the treatment of childhood illnesses and disorders (otitis media, colds, chronic fatigue syndrome, ADHD, etc.); examine infrequently used techniques in the treatment of childhood conditions of pain or stress (suggestive relaxation techniques for migraine headaches and other painful conditions, massage therapy for infants born at risk, acupuncture, hypnosis, etc.); examine children's understanding of health and illness and how that understanding relates (translates) to health behavior; study the behavioral treatment of sleep disorders in children and adolescents; examine the impact of mind/body interactions on the physiology of pregnancy and the infant in relation to health outcome; study the effects of mind/body interactions on fertility, maternal health during pregnancy, labor, delivery and postpartum periods, breast feeding patterns, and nurturing and rearing of infants and children by both parents- especially, fathers; examine the role of health-related beliefs or attitudes on achieving and maintaining health and well-being of children and youth with physical, learning or developmental disabilities; examine mind/body interactions in children with physical disabilities caused by injury and their adaptation to the impairments.

o NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

NIDCR encourages studies that investigate mind-body interactions with regard to oral and craniofacial diseases and disorders or dental treatments. Examples include, but are not limited to studies of the effects of beliefs, affective states, or stress on the immune system as related to the onset, progression, or treatment of oral diseases/conditions such as the periodontal diseases,

caries, head and neck cancers, temporomandibular joint and/or muscle disorders, herpetic and aphthous lesions, oral manifestations of HIV infection, or oral mucosal wound healing following oral surgery. Stress as a result of living with craniofacial anomalies such as cleft lip and cleft palate and disfigurement following treatment of head and neck cancers may also have an adverse effect on the immune system and treatment outcomes; studies examining these linkages and interventions to improve outcomes are encouraged. The NIDCR also encourages studies that integrate oral biomarkers into the evaluation of effects of stress-management or other therapeutic interventions. Changes in salivary composition and flow are examples of oral biomarkers shown to be relevant to stress and its physiological impact. The relative accessibility of the oral cavity provides unique opportunities for non-invasive studies of psychophysiological responses associated with positive or negative life events, acute or chronic stress-inducing conditions, and psychological characteristics or psychiatric conditions.

o NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

The NIDDK is interested particularly in mind-body and health research related to (a) obesity and (b) functional bowel disorders. Examples relevant to OBESITY are: The influence of social stress, depression, anxiety, fear, and insecurity leading to or resulting from significant life events such as divorce, job loss, economic deprivation, social discrimination, and related factors that predispose individuals to inappropriate eating behaviors, inappropriate sedentary behaviors, and inadequate physical activity behaviors associated with the development of overweight and obesity. The role of self-confidence, self-esteem, self-efficacy, self-motivation, self-image, self-perception, religiosity/faith, social and family support networks, anger, conflict resolution, cultural beliefs, and related factors in the primary prevention of inappropriate weight gain, weight maintenance in those already overweight, and prevention of weight regain in those who have lost weight. Psycho-social factors that stimulate motivation and lead to behavioral changes whereby individuals accept a greater responsibility for their personal dietary and physical activity health behaviors in the context of a challenging environment that promotes overeating and sedentary behaviors. Psycho-social factors associated with unfavorable behaviors such as night eating, binge eating, food cravings, or sedentary behaviors such as television watching that lead to energy imbalance attributable to excess caloric consumption and/or insufficient energy expenditure. Examples relevant to FUNCTIONAL BOWEL DISORDERS are: The influence of gestational hormonal changes and its influences on visceral hypersensitivity in the setting of functional bowel disorders. Studies on the role of peptide hormones released in the circulation in response to either stress, chemical, or mechanical stimulation of the gut mucosa may provide insights into treatment options for patients with functional bowel disorders. Comparisons of the efficacy of non-pharmacological (i.e. Cognitive behavioral therapy, hypnosis) to pharmacological approaches in the management of functional bowel disorders. Research on psychosocial factors

such as depression, low self-esteem, isolation, and how they impact on disease expression and severity and quality of life of patients who have irritable bowel syndrome and other functional gastrointestinal disorders.

o NATIONAL INSTITUTE OF MENTAL HEALTH

The mission of NIMH is to reduce the burden of mental illness and behavioral disorders through research on mind, brain, and behavior. With regard to this RFA, the following are illustrative topics: Mechanisms accounting for the co-occurrence and co-morbidity of mental disorders with physical disorders; identification of principles motivating and sustaining behavior changes to reduce the risk for co-occurring mental and physical disorders; relationships of pain to mental disorder; interventions to prevent the occurrence of mental health problems in individuals with physical disorders; tests of innovative treatments for individuals with co-occurring mental and physical disorders; social, psychological, and neurobiological factors underlying stress responsivity; "social neuroscience" investigations to uncover mechanisms underlying effects of interpersonal, social and other environmental factors on mental and physical health and disease; influences of cognitive, personality, interpersonal and cultural factors on perceptions of risk, help-seeking, symptom reporting and health-related behavior; identification of neural substrates underlying cognitive functions that influence emotional and stress reactivity; and identification of hormonal, biochemical, and cellular pathways mediating effects of stress and illness on cognition and mood. Experimental approaches should encompass the range of cutting-edge methods in social and behavioral science as well as neuroscience.

o NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

The NINDS is interested in mind-body research relevant to: 1) development of research strategies for stroke prevention and appropriate management of recurrent stroke (behavior modification; life style changes, role of psychosocial variables like stress, depression, coping skills, social support/social isolation); 2) development and evaluation of rehabilitation interventions for neurological disorders (stroke, TBI, neurodegenerative disorders) - physiological behavioral and social pathways influencing rehabilitation outcomes; 3) behavioral and psychosocial intervention in randomized clinical trials of neurological disorders (epilepsy, stroke, TBI, neurodegenerative) - interactions of behavioral and biomedical treatments.

o NATIONAL INSTITUTE ON AGING

The NIA's mission is to improve the health and well-being of older Americans through research. The NIA is interested in a developmental life-course perspective of aging and mind-body effects on acute and chronic health, quality of life, functional capacity, and life expectancy/mortality. How diseases common in late-life (e.g. hypertension, Type II diabetes, osteoarthritis, Alzheimer's

disease) are modulated by physiological, neurological, cognitive, affective, perceptual, and psychosocial factors experienced by the older individual is of high interest. Research on how mind-body processes affect health disparities is especially encouraged, as is multilevel/multi-system and interdisciplinary research. Illustrative examples include: mind-body effects on longevity; early life experiences mediated via mind-body interactions and their effects on late life health; mind-body effects that are predictive of adherence to and benefit from an intervention; the cumulative effects of stress on the health of the elderly; the impact of optimism, happiness, or a positive attitude on well-being and health; the cognitive impact of social exclusion and disruptions to social functioning on health; the percepts and affective responses to one's socioeconomic and occupational environment and their effects on health; and the cumulative impact of extreme stress on health in low resource/low income and in-transition countries.

o NATIONAL INSTITUTE ON DRUG ABUSE

NIDA is interested in supporting research that investigates the role of cognitive and/or emotional variables mediating or moderating the development of drug abuse and addiction. NIDA is interested in the initiation of drug abuse ("chipping" or occasional drug use), the maintenance or continuation of drug taking behaviors (chronic abuse, including escalation to compulsive abuse and its associated negative consequences), relapse, and characteristics of sustained abstinence. The study of cognitive and/or emotional factors (e.g., self-regulation, beliefs, self-attributes, perceived risks or benefit), that influence vulnerability or resilience to drug abuse, is also of interest. To address these questions, investigators may study responsivity to acute drug challenge, including the examination of how physiological, motivational or subjective responses to drugs of abuse are influenced by cognitive and emotional variables (e.g., expectancy, affective state, emotional context, etc.). Also appropriate would be studies examining cognitive and emotional variables (e.g., coping, emotional regulation, self-efficacy) in the context of treatment or preventive interventions (e.g., role in adherence or compliance), including studies on the influence of media and other forms of informational messages. The study of decisions and other cognitive processes, and their associated neural substrates, which give rise to sexual risk behavior, is also an area of research interest. Studies on the influence of physiological indicators of stress, stress perception or stress reactivity (e.g., allosteric load) on drug abuse vulnerability or clinical outcome, may be included in proposed investigations. Studies in response to this RFA may be laboratory-based experiments (i.e., with human substance abusing populations, or preclinical models), or field based investigations in real world or clinical settings.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH)

Exploratory/Developmental Grant (R21) mechanism for Developmental Awards. The R21 mechanism is used to encourage the development of promising research programs. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. This RFA is a one-time solicitation. Currently, NIH does not have a plan for re-issuing this RFA within the next five years.

The total project period for an application submitted in response to this RFA is up to three (3) years. R21 awards are non-renewable. The anticipated award date is April 2004.

This RFA uses just-in-time concepts and the modular budgeting format. (See <http://grants.nih.gov/grants/funding/modular/modular.htm>). Modifications to the standard application instructions, which are provided under SUPPLEMENTAL INSTRUCTIONS below, must be used when preparing applications in response to this RFA.

Institutions applying for a Developmental Award (R21) may request support for (1) Research Support Activities and (2) Developmental Activities. Although applicant institutions may NOT request support for R01-like research projects, they may request support for developmental research projects, similar to a pilot or small grant mechanism. Applicant institutions must justify the types and amounts of support requested in terms of: (a) the scope, objectives, and current and potential impact of the institution's research program; (b) the potential of the requested infrastructure to develop the resources and mechanisms required to build a substantial interdisciplinary portfolio of mind-body and health research and facilitate significant new contributions to the field; and (c) the cost-effectiveness of the requested support.

1. RESEARCH SUPPORT ACTIVITIES provide shared resources that support the institution's research program. Research Support Activities should be designed to advance the central scientific objectives and themes of the applicant institution's research program while providing essential, cost-effective services to support on-going research activities. Activities and organizational structures should be designed to facilitate and promote innovation in the science conducted by program researchers in addition to responding to researcher needs. Equipment and support services that are specific to (i.e., solely for) individual research projects or researchers are not allowable. Examples include:

- o ADMINISTRATIVE CORE, providing for coordination of research, editorial services, and/or assistance with grant application development and fiscal management of grants.

- o COMPUTING CORE, providing equipment and/or services supporting shared computing needs.

- o INFORMATION CORE, providing support for retrieving information, materials, and data commonly used in mind-body and health research.

- o DESIGN, ANALYSIS, AND DATA SHARING CORES, providing support for methodological and statistical issues as well as the preparation and implementation of data sharing among investigators within and outside of the applicant institution.

2. DEVELOPMENTAL ACTIVITIES promote the improvement and expansion of research capabilities. Examples include:

- o PILOT RESEARCH SUPPORT, providing funds for the development of new research projects. Institutions proposing pilot research programs must develop guidelines and eligibility requirements appropriate to the goals of this RFA, and procedures and policies for administration of the program. Issues that may be addressed include (but need not be limited to): (1) priorities for allocating funds (e.g., junior researchers, specified areas of research, interdisciplinary work, etc.); (2) procedures for reviewing applications; (3) requirements for leveraging funds or preparing research proposals to continue or expand the research project; (4) size of awards; (5) length of award periods; (6) number of awards permitted to an individual researcher; (7) mentoring arrangements; and (8) cost-sharing arrangements with the parent institution.

- o FACULTY DEVELOPMENT, providing for partial salary support or other support for the recruitment of new faculty in scientific areas critical to the development of innovative and/or interdisciplinary research directions (support for any one individual may not exceed three years in duration); and/or training for faculty at alternative laboratories of collaborative research units.

- o NEW SERVICES, fostering the development of new core services. For example, applicant institutions may propose to hire consultants to assist with the design of research data acquisition services, or conduct pilot studies to evaluate the cost-effectiveness of alternative modes of core service delivery.

- o RESEARCH AGENDA DEVELOPMENT, laying the groundwork for new substantive work or foster new research collaborations through workshops, conferences, seminar series, and visiting scholar programs; hosting scientists of collaborative research units to facilitate grant writing; meetings of interdisciplinary collaborators. The purpose of these activities and meetings should

be to refine conceptual frameworks for organizing cross-disciplinary research projects and identifying which specific research questions and experiments show the greatest promise for advancement in the field of "Mind-Body" research.

FUNDS AVAILABLE

The NIH intends to commit approximately \$2 million in total costs [Direct plus Facilities and Administrative (F & A) costs] in FY 2004. The NIH anticipates making up to four awards. Although the financial plans of the NIH provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. At this time, it is not known if this RFA will be reissued.

Because the nature and scope of the research proposed may vary, it is anticipated that the size of each award will also vary. Applicant institutions may request a project period of up to three years and a budget for DIRECT costs of up to \$300,000 per year.

Applicant institutions are strongly encouraged to discuss budget requests with program staff listed under INQUIRIES prior to submission.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Eligible agencies of the Federal government
- o Domestic (foreign institutions are ineligible)
- o Faith-based or community-based organizations.

To be eligible the applicant institution must have at least three (3) researchers with a history of research activity related to mind-body and health research in both of the following categories: (1) externally funded research grants or contracts in the past three years and (2) one or more publications in peer-reviewed journals during the past three years. The "past three years" refers to the 36-month period preceding the application submission date for this RFA. "Externally funded" means funding is received from sources outside the institution; it may include peer-reviewed funding from NIH, NSF, other federal agencies, state and local governments, and

private foundations. Include only projects on which the individual has served as Principal Investigator or had substantial involvement, comparable to that indicated by identification of an investigator as "key personnel" on an NIH-funded grant.

Eligibility for R21 Developmental Infrastructure Awards is restricted to institutions that have not held a P30 or P50 grant related to mind-body and health research in the five years prior to the application date. Institutions may not submit simultaneous applications in response to this RFA and to [RFA-OB-03-004](#) MIND-BODY INTERACTIONS AND HEALTH: DEVELOPMENTAL INFRASTRUCTURE PROGRAM (for R24 awards).

Potential applicant institutions are strongly encouraged to contact staff listed under INQUIRIES to discuss eligibility prior to submission of an application.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

Applicant institutions must already have in place or establish at the time of an award a research center or other administrative unit (referred to as the "research unit" or "unit") that serves as a focal point for or coordinates mind-body and health research across the institution. This unit must have a defined governance structure. The Principal Investigator should be a scientist or science administrator who can provide effective administrative and scientific leadership. Because the "Mind-Body Interactions and Health: Developmental Infrastructure Program" is expected to enhance the unit's competitiveness for NIH funding, the institution and pertinent departments are expected to show a strong commitment to the unit and to match the requested infrastructure support at a level appropriate to the resources of the institution and the scope of the proposed program activities. Such commitment may be demonstrated by the provision of dedicated space, faculty appointments in subject areas relevant to the goals of the unit's research program, salary support for investigators or core staff, dedicated equipment, or other financial support for the proposed program. Applicant institutions are encouraged to consult with program staff listed under INQUIRIES to discuss this requirement.

The research conducted at the unit should reflect scientific benefits and cost-efficiencies resulting from cooperation and interaction among a pool of scientists with shared interests in mind-body and health research. Applicant institutions should have in place (or propose in their applications) effective mechanisms for fostering the development of an intellectual community that bridges investigators from different disciplines and different projects and promotes innovation in mind-body and health research.

Also see ELIGIBLE INSTITUTIONS (above) for minimum application requirements. Note that these requirements take precedence over requirements announced elsewhere (e.g., in the instructions for the application kit PHS 398).

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

- o Direct inquiries regarding GENERAL ISSUES to:

Ronald P. Abeles, Ph.D.
Office of Behavioral and Social Research
Office of the Director
National Institutes of Health
Gateway Building, Room 2C234, MSC 9205
7201 Wisconsin Avenue
Bethesda, MD 20892-9205
Phone: 301-496-7859
E-mail: abeles@nih.gov

- o Direct inquiries regarding research interests and topics of specific INSTITUTES AND CENTERS to:

FORGARTY INTERNATIONAL CENTER

Flora N. Katz, Ph.D.
Fogarty International Center
National Institutes of Health
31 Center Drive

Bethesda, MD 20892-2220

Phone: 301-402-9591

Fax: 301-402-0779

E-mail: katzf@mail.nih.gov

NATIONAL CANCER INSTITUTE

Michael Stefanek, Ph.D.

Chief, Basic Biobehavioral Research Branch

Behavioral Research Program

Division of Cancer Control and Population Sciences

National Cancer Institute

6130 Executive Boulevard/EPN 4066

Bethesda, Maryland 20892

Phone: 301-496-8776

Fax: 301-435-7547

E-mail: ms496r@nih.gov

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Nancy J. Pearson, Ph.D.

National Center for Complementary and Alternative Medicine

National Institutes of Health

6707 Democracy Blvd., Room 401

Bethesda, MD 20892

Phone: 301-594 0519

E-mail: pearsonn@mail.nih.gov

NATIONAL EYE INSTITUTE

Chyren Hunter, Ph.D.

National Eye Institute, NIH

6120 Executive Blvd., MSC 7164

Executive Plaza South, Suite 350

Bethesda, MD 20892-7164

Phone: 301-451-2020

Fax: 301-402-0528

E-mail: clh@nei.nih.gov

NATIONAL HEART, LUNG AND BLOOD INSTITUTE

Sarah Knox, Ph.D.
Behavioral Medicine Research Group
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
6701 Rockledge Drive - MSC 7936
Bethesda, MD 20892-7936
Phone: 301-435-0409
E-mail: knoxs@nhlbi.nih.gov

NATIONAL INSTITUTE OF ALCOHOL ABUSE AND ALCOHOLISM

Thomas Gentry, Ph.D.
Office of Collaborative Research
National Institute on Alcohol Abuse and Alcoholism
6000 Executive Boulevard MSC 7003, Suite 302
Bethesda, MD 20892-7003
Phone: 301-443-6009
Fax: 301-480-2358
E-mail: tgentry@mail.nih.gov

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Christopher E. Taylor, ScD
Bacterial Diseases Program Officer
Respiratory Diseases Branch
Division of Microbiology & Infectious Diseases
NIAID
6700-B Rockledge Drive
Bethesda, MD, 20852-7630
Phone: 301-496-5305
Fax: 301-496-8030
E-mail: ct18m@nih.gov

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Deborah N. Ader, Ph.D.
Behavior and Prevention Research Program Director
One Democracy Plaza, Suite 800
Bethesda, MD 20892-4872
Telephone: 301-594-5032

Fax: 301-480-4543

E-mail: aderd@mail.nih.gov

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

V. Jeffery Evans Ph.D., J.D.

Director of Intergenerational Research

Demographic and Behavioral Sciences Branch

National Institute of Child Health and Human Development

6100 Executive Boulevard, Room 8B07, MSC 7510

Bethesda, MD 20892-7510

Phone: 301-496-1176

Fax: 301-496-0962

E-mail: evansvj@mail.nih.gov

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Patricia S. Bryant, Ph.D

Director, Behavioral and Social Sciences Research Program

Clinical, Epidemiology, and Behavioral Research Branch

Division of Population and Health Promotion Sciences

National Institute of Dental and Craniofacial Research

45 Center Drive, Rm 4AS.43A

Bethesda, MD 20892-6402

Phone: 301-594-2095

Fax: 301-480-8322

Email: Patricia.Bryant@nih.gov

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Frank A. Hamilton, M.D., MPH

Director, GI Motility Program

Division of Digestive Diseases and Nutrition

NIDDK

6707 Democracy Boulevard, Democracy 2

Bethesda, Maryland 20892-5450

Phone: 301-594-8877

Fax: 301-480-8300

E-mail: hamiltonf@ep.niddk.nih.gov

NATIONAL INSITUTE OF MENTAL HEALTH

Mary Ellen Oliveri, Ph.D.

Chief, Behavioral Science Research Branch

Division of Neuroscience and Basic Behavioral Science

National Institute of Mental Health

6001 Executive Boulevard, Room 7220, MSC 9651

Bethesda, MD 20892

Phone: 301-443-3942

Fax: 301-443-9876

E-mail: moliveri@nih.gov

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Emmeline Edwards, Ph.D.

Systems and Cognitive Neuroscience Program

National Institute of Neurological Disorders and Stroke

6001 Executive Boulevard R2109

Bethesda, MD 20892-9521

Phone: 301-496-9964

Fax: 301-402-2060

E-mail: ee48r@nih.gov

NATIONAL INSTITUTE ON AGING

Richard Suzman, Ph.D.

Associate Director

Behavioral and Social Research (BSR)

Gateway Building, Suite 533

7201 Wisconsin Avenue, MSC 9205

Bethesda, MD 20892-9205

Phone: 301-496-3131

Fax: 301-402-0051

E-mail: SuzmanR@nia.nih.gov

NATIONAL INSTITUTE ON DRUG ABUSE

Ro Nemeth-Coslett, PhD

National Institute on Drug Abuse

Division of Treatment Research and Development

Clinical Neurobiology Branch

NSC Rm 4234 MSC 9551
6001 Executive Blvd,
Bethesda, MD 20897
Phone: 301-402-1746
Fax: 301-443-6814
E-mail: rn29e@nih.gov

o Direct your questions about PEER REVIEW ISSUES to:

Michael Micklin, Ph.D.
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Rm. 3178 MSC 7848
Bethesda, MD 20814-9692
Phone: 301-435-1258
Fax: 301-480-3962

o Direct your questions about FINANCIAL OR GRANTS MANAGEMENT MATTERS to:

FORGARTY INTERNATIONAL CENTER
Bruce Butrum
Fogarty International Center
National Institutes of Health
31 Center Drive
Bethesda, MD 20892-2220
Phone: 301-496-1670
Fax: 301-594-1211
E-mail: butrumb@mail.nih.gov

NATIONAL CANCER INSTITUTE
Crystal Wolfrey
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, Maryland 20892
Phone: 301-496-8634
E-mail: wolfreyc@mail.nih.gov

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Victoria Carper

Grants Management Officer

National Center for Complementary and Alternative Medicine

National Institutes of Health

6707 Democracy Blvd., Room 401

Bethesda, MD 20892

Phone: 301-594-9102

E-mail: carperv@nccam.nih.gov

NATIONAL EYE INSTITUTE

William W. Darby

Grants Management Officer

National Eye Institute

Executive Plaza South, Suite 350

6120 Executive Blvd, MSC 7164

Bethesda, MD 20892

Phone: 301-451-2020

Fax: 301-496-9997

E-mail: wwd@nei.nih.gov

NATIONAL HEART, LUNG AND BLOOD INSTITUTE

Tanya McCoy

Grants Operations Branch

Division of Extramural Affairs

National Heart, Lung, and Blood Institute

6701 Rockledge Drive - MSC 7926

Bethesda, MD 20892-7926

Phone: 301-435-0171

E-mail: mccoyt@nhlbi.nih.gov

NATIONAL INSTITUTE OF ALCOHOL ABUSE AND ALCOHOLISM

Judy Fox

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National Institute on Alcohol Abuse and Alcoholism

Willco Building, Suite 505

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Bethesda, MD 20892-7003

Phone: 301-443-2434

E-mail: simons@willco.niaaa.nih.gov

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Lesia A. Norwood

Grants Management Officer

Grants Management Branch

Division of Extramural Activities

National Institute of Allergy and Infectious Disease

6700-B Rockledge Drive, Room 2117, MSC 7614

Phone: 301-402-7146

Fax: 301-480-3780

E-mail: ln5t@nih.gov

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

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6701 Democracy Blvd.

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E-Mail: MorseM@mail.nih.gov

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Kathy Hancock

Grants Management Branch

National Institute of Child Health and Human Development

6100 Executive Boulevard, Room 8A17K, MSC 7510

Bethesda, MD 20892-7510

Phone: 301-496-5482

Fax: 301-480-4782

E-mail: hancockk@mail.nih.gov

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

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45 Center Dr MSC 6402
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Phone: 301-594-4808
Fax: 301-480-8303
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NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
Mr. Donald Ellis
Grants Management Branch. NIDDK
6707 Democracy Boulevard, Room 743
Bethesda, Maryland 20892-5450
Phone: 301-594-8849
Fax: 301-480-3504
E-mail: ellisd@ep.niddk.nih.gov

NATIONAL INSTITUTE OF MENTAL HEALTH
Diana S. Trunnell
Assistant Chief, Grants Management Branch
Division of Extramural Activities
National Institute of Mental Health
6001 Executive Boulevard, Room 6120, MSC 9605
Bethesda, MD 20892-9605
Phone: 301-443-2805
Fax: 301-443-6885
E-mail: dtrunnel@mail.nih.gov

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE
Rita Sisco
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National Institute of Neurological Disorders and Stroke
6001 Executive Boulevard R3265
Bethesda, MD 20892
Phone: (301) 496-7488
Fax: (301) 402-0219
E-mail: rr46w@nih.gov

NATIONAL INSTITUTE ON AGING

Linda Whipp

Grants and Contracts Management Officer

National Institute on Aging

Gateway Building, Suite 2N212

7201 Wisconsin Avenue, MSC 9205

Bethesda, MD 20892-9205

Phone: 301-496-1472

Fax: 301-402-3672

Email: whipp@nia.nih.gov

NATIONAL INSTITUTE ON DRUG ABUSE

Gary Fleming, J.D., M.A.

National Institute on Drug Abuse

Office of Planning and Resource Management

Grants Management Branch

6001 Executive Boulevard, Room 3131

MSC 9541

Bethesda, MD 20892

Phone: (301) 443-6710

Fax: (301) 594-6849

E-mail: gffleming@mail.nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

- o Descriptive title of the proposed research
- o Name, address, and telephone number of the Principal Investigator
- o Names of other key personnel
- o Participating institutions
- o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by June 16, 2003. The letter of intent should be sent to:

Ronald P. Abeles, Ph.D.
Office of Behavioral and Social Research
Office of the Director
National Institutes of Health
Gateway Building, Room 2C234, MSC 9205
7201 Wisconsin Avenue
Bethesda, MD 20892-9205
Phone: 301-496-7859
E-mail: abeles@nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone 301-435-0714, Email: GrantsInfo@nih.gov.

SUPPLEMENTAL INSTRUCTIONS

Applications for the R21 must be prepared according to Modular Grant instructions. The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and Institute staff. The research grant application form PHS 398 (rev. 5/01) is to be used in applying for these grants, with the modifications noted below.

For responses to this RFA, Modular Grant applications will request direct costs in \$25,000 modules, up to a maximum Direct Cost request of \$300,000 per year for a maximum of three years. The Direct Costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below.

In lieu of the preprinted Table of Contents outline on Form Page 3 of PHS 398, a table of contents should be prepared listing all of the major sections described below and paginated to enable

reviewers to find specific information readily. The Table of Contents should contain the types of information suggested below in three sections: Section I - General Information, Section II - Research Plan, and Section III - Appendix. The following guidelines will provide directions and descriptions for preparing each section. Major areas to be listed and paginated in the Table of Contents appear in capital letters.

SECTION I. GENERAL INFORMATION

A. FACE PAGE

This is page 1; number succeeding pages consecutively.

Items 7a and 7b should be completed, indicating Direct Costs (in \$25,000 increments to a maximum of \$300,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period.

Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support (up to three years).

The RFA title ("Mind-body Interactions and Health: Developmental Infrastructure Program") and number (OB-03-005) must be typed on line 2 of the face page and the YES box must be marked.

B. DESCRIPTION AND PERSONNEL

Abstract of Research Plan. On page 2, describe briefly the objectives of the proposed developmental grant and the proposed infrastructure components. The abstract should fit in the space provided.

List key scientific and technical personnel participating in the grant.
Use continuation pages as necessary, numbering consecutively.

C. TABLE OF CONTENTS

Prepare the Table of Contents as noted above. The major areas to be listed are enumerated in these instructions.

D. BUDGET ESTIMATES

- o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD: Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

- o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT: Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

- o NARRATIVE BUDGET JUSTIFICATION: Prepare a Modular Grant Budget Narrative page. (See <http://grants.nih.gov/grants/funding/modular/modular.htm> for sample pages.) At the top of the page, enter the total direct costs requested for each year. This is not a Form Page.

Provide an estimate of direct costs associated with each proposed infrastructure component.
Provide requested information on personnel separately for each infrastructure component.

- o Under PERSONNEL, list all project personnel, including their names, percent of effort, and roles on the project. Describe the specific functions of key scientific and technical personnel, consultants, collaborators, and support staff. No individual salary information should be provided. However, the applicant should use the NIH appropriation language salary cap and the NIH policy for graduate student compensation in developing the budget request.

- o For CONSORTIUM/CONTRACTUAL COSTS, provide an estimate of total costs (direct plus F & A) for each year, each rounded to the nearest \$1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project.

Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount. Include the Letter of Intent to establish a consortium.

- o Provide an additional narrative budget justification for any variation in the number of modules requested.

- o Budget estimates must include travel costs for attending an ANNUAL MEETING of project directors and key staff at the NIH in Bethesda, Maryland. Budget at least for two persons to attend a two-day meeting once per year.

E. BIOGRAPHICAL SKETCH

The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key scientific and technical personnel, following the instructions below. List key scientific personnel first, beginning with the Principal Investigator, and following in alphabetical order. Then list all technical personnel involved in infrastructure components of the application in alphabetical order. No more than four pages may be used for each person. A sample biographical sketch may be viewed at: <http://grants.nih.gov/grants/funding/modular/modular.htm>. Note that this information is essential in demonstrating that the applicant institution meets eligibility requirements for a R21 award. (See ELIGIBLE INSTITUTIONS, above.)

- o Complete the educational block at the top of the form page.
- o List position(s) and any honors.
- o Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years.
- o List selected peer-reviewed publications, with full citations.

F. OTHER SUPPORT

Not required for modular grant application.

G. SUMMARY TABLE OF RESEARCH SUPPORT

Applicants should present a summary table of the levels of infrastructure and research support received by the unit, by source. This table should show, for the applicant unit as a whole, the total funds supporting research and infrastructure in the unit for the most recent budget year available. Show sources of funds in major categories (e.g., NIH P30, R03, or R01 grants, NSF, Foundations, parent institution, etc.). This table should be presented in a format of the example available at http://obssr.od.nih.gov/RFA_PAs/MBFY04/Research_Support_Table.htm.

H. RESOURCES AND ENVIRONMENT

Complete the RESOURCES section on Form Page 8 for the overall unit. Briefly describe the features of the institutional environment that are or would be relevant to the effective

implementation of the proposed program. As appropriate, describe available resources, such as clinical and laboratory facilities, participating and affiliated units, patient populations, geographical distribution of space and personnel, and consultative resources. Use continuation pages as needed.

CHECKLIST: This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

SECTION II - RESEARCH PLAN

Include a detailed Table of Contents with pagination (numeric only) at the beginning of Section II. Identify each section by title, and assign each a capital letter (A, B, C, etc.) that reflects the order in which they are presented in the application research plan.

Page limitations: The length of the sections devoted to the overall description of the program, progress report, research activity, and proposed infrastructure components must not exceed those specified below. Applicants should be concise.

Assurances and Collaborative Agreements. Any arrangements for collaborative and cooperative endeavors or subcontracting should be highlighted in the appropriate section below. Letters of Intent to Collaborate and Letters of Agreement from consultants should be referenced here and included at the end of the appropriate component.

A. PROGRAM OVERVIEW

Summarize the central scientific objectives and themes of the unit. Highlight significant, unique, and/or cross-cutting areas of research. Describe the impact the unit has had on the field with reference to major recent contributions by active researchers in the program, large-scale projects that exhibit positive externalities in the field, creation of interdisciplinary collaborations, training and mentoring of new scientists, scientific leadership of program personnel, and translational activities to improve clinical practice, public intervention programs, and public policy formulation.

Summarize the vision of program researchers for the unit's future scientific advances and contributions.

Describe the configuration and governance of the unit and provide an organizational chart. Include information on administrative position of the unit within the larger institution, the authority of the Director, and the use of advisory or user committees. Outline the principles and procedures the unit uses to determine membership in or affiliation with the unit and to allocate resources and grant access to core services. If the unit employs more than one category of membership or affiliation, explain the privileges and responsibilities associated with each. Describe how the NIH support would leverage and interact with all other forms of support contributing to the research activities of the program.

Describe strategies the unit employs for advancing the quality and innovation of its mind-body and health research program over the short and long run. Describe how the unit fosters the development of an intellectual community that bridges investigators from different disciplines and different projects and promotes innovation in mind-body and health research. Describe how the unit develops and implements its goals. Describe how the unit assures the development and success of junior scientists.

Summarize the key features of the proposed developmental program and explain how each element will advance the quality, productivity, and innovation of the unit's research activities.

Do not exceed 10 pages for this section.

B. PROGRESS REPORT

Not required.

C. SCIENTIFIC OBJECTIVES AND THEMES

Describe the themes of the unit's research program and its central scientific objectives for advancing research on these themes. For each highlighted theme:

Discuss the scientific and practical significance of the research theme: how can advances in this area contribute to substantive knowledge, scientific methods, or public well-being?

Describe how current and recent research activity in the unit has contributed to the theme: what scientific accomplishments have program scientists achieved and how have they affected mind-body and health research? Highlight activities that have produced significant innovation and/or interdisciplinary collaboration.

Describe the vision of program scientists for advancing research on this theme. What are the important questions to be answered? What challenges must scientists overcome to answer them? What specific objectives will guide the work of program scientists in this area?

What strategies will program scientists adopt to meet the challenges and objectives relating to this theme? Include discussion of how the proposed infrastructure components will advance research in this area.

Do not exceed 15 pages for this section.

D. RESEARCH ACTIVITY OF PROGRAM SCIENTISTS

Briefly summarize the recent and current research activity of each active program scientist with respect to each of the five points listed below. Use one page per active researcher. Describe the Principal Investigator's research activity first and that of all other researchers subsequently in alphabetical order.

1. Summarize the most important scientific accomplishments of the researcher during the 36 months prior to the receipt date for this RFA (i.e., July 2000 – July 2003). Discuss these accomplishments with respect to their significance, innovation, and actual or potential impact on mind-body and health research.
2. Identify externally funded research projects in which the researcher participated as key personnel during the 36 months prior to the receipt date for this RFA, the amount, source, and period of funding, and the role and time commitment of the individual on the project. Information provided in the BIOGRAPHICAL SKETCH may be referenced as appropriate to avoid repetition.
3. Briefly summarize relevant working papers and future research plans (e.g., pending and planned research grant applications).
4. Describe how the researcher contributes to the unit's research program: how his or her expertise, disciplinary training, substantive interests, technical skills help to advance the central

scientific objectives and themes of the unit. Identify recent, active, or planned collaborations involving this researcher.

5. Describe how the researcher uses (or would use) the proposed cores or activities.

E. COMPONENT DESCRIPTIONS

Describe proposed components in the order listed below. If more than one component is proposed under a given category, assign letters to distinguish the components (e.g., 1.a; 2.c). For each component, provide the name of the Director and describe procedures used to assure cost-efficiency and high quality administrative and research activities.

Do not exceed five pages in describing each component (core or activity), excepted as noted below. If any component is described as a collaborative activity (i.e., involving partnership with another institution), applicants may use one additional page to describe how each partner will contribute (e.g., in terms of administration, staffing, and other resources); how each partner will benefit (e.g., in terms of access to services or research productivity); and how decision-making will be shared.

1. Research Support Activities - Describe the objectives, administrative organization (use organizational chart), staffing (including a Core Director and any professional or technical personnel and their duties, space and physical resources, current and projected services, eligibility for and allocation of services, and cost-sharing arrangements. Briefly describe current or planned research activities that will utilize the core services.

Explain how the proposed research support activities and organizational structures will contribute to advancing the central scientific objectives and themes of the research program and how the activities will foster innovation in the program's research. Describe strategies for assuring that research support services effectively respond to and anticipate the evolving needs of science conducted in the unit. Justify the core in terms of scientific impact and cost-effectiveness. Explain what the proposed services will provide over and above research support that the applicant's institution already provides and why they are essential to meet the needs and goals of the research program.

2. Developmental Activities - Describe the objectives and administrative organization of each type of developmental activity and organizational structure. Describe the impact of the activity on mind-body and health research within the unit. In describing a seed-grant program, include

information on the pilot or small research projects selected for implementation in the first year (maximum one-page per project). Then provide details on program procedures and policies (maximum five pages), including review procedures; priorities for allocating funds; requirements for leveraging funds or preparing research proposals to extend or continue the project; size of awards; length of award periods; number of awards permitted to an individual researcher; mentorship arrangements; and cost-sharing arrangements with the parent institution.

Faculty development may include salary and/or research support for new faculty. Describe the probable use of faculty development funds and the ways in which the plan will advance the unit's research objectives.

SECTION III: APPENDIX

Follow the standard guidelines for an appendix:

http://grants.nih.gov/grants/funding/phs398/section_1.html#9_appendix.

Do not use the appendix to circumvent page limitations. The appendix will not be duplicated with the application and will be sent only to certain members of the SRG who will serve as the primary reviewers of the application.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title (Mind-Body Interactions and Health: Developmental Infrastructure Program) and number (OB-03-005) must be typed on line 2 of the face page of the application form and the YES box must be marked.

The RFA label is also available at: <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and five signed, photocopies, in one package to:

Center For Scientific Review
National Institutes Of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received by July 16, 2003. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the Office of Behavioral and Social Sciences Research (OBSSR). Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the CSR in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

- o Receive a written critique
- o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
- o Receive a second level review by the National Advisory Council or Board of the NIH Institute or Center to which it is assigned.

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of health-related biological, behavioral, and social systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of each project in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of the criteria listed below will be addressed and considered in assigning the score for a research project, weighting them as appropriate for each project. Note that the project does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score.

A. OVERALL PROGRAM

One PRIMARY CRITERION will be used to evaluate the overall scientific merit of an application for a Developmental Award (R21): The potential future contributions of the applicant program to mind-body and health research.

Reviewers will base their assessment of potential on such factors as the current level and trajectory of research productivity, innovation, quality and significance; the significance of the applicant institution's central scientific objectives and themes and the plan for advancing them; the program's plan for encouraging synergy and interaction among mind-body and health researchers; and the applicant institution's success in contributing to the development of junior investigators.

Three SECONDARY CRITERIA will also be used to assess the overall scientific merit of applications:

a) Quality and potential impact of proposed infrastructure program: Reviewers will examine the overall quality, scientific merit, and innovation of the activities to be supported. Reviewers will consider the likelihood, based on existing capabilities and proposed activities, that the proposed program will develop the resources and mechanisms required to build a substantial interdisciplinary portfolio of mind-body and health research and facilitate significant new contributions to the field.

b) Research competence of key personnel: Reviewers will consider the capability and scientific credentials of the Principal Investigator to direct the program and maintain high standards of research collaboration; the specific technical qualifications of core directors; and the scientific accomplishments of all participating investigators.

c) Institutional commitment and environment: Reviewers will assess the nature and level of resource commitment from the institution in which the center is housed and any cooperating institutions, taking into account the institutional context. Reviewers also will consider the academic and physical environment as it bears on research opportunities, space, equipment, and the potential for interaction with scientists from various departments, institutions or disciplines.

B. EXPLORATORY/DEVELOPMENTAL RESEARCH COMPONENTS:

Individual elements of the proposed program will be evaluated separately based on the criteria below.

1. Research Support Activities

- o Potential or actual contribution of the proposed activity to advancing research within the applicant unit, by: enhancing the productivity of the existing scientific program; fostering new scientific advances; facilitating interactions across disciplines and substantive areas of study; and/or advancing theoretical or technical approaches.
- o Appropriateness to the size and characteristics of the applicant institution's existing research program and the central scientific objectives and themes of the program.
- o Qualifications, experience, and commitment to the program of the investigators responsible for the cores or activities and their ability to devote the required time and effort to the program.
- o Cost-effectiveness of services or activities and appropriateness of cost-sharing arrangements with the institution, relevant departments, and other external infrastructure support programs.

2. Developmental Activities

- o Potential of the proposed activity to advance research within the applicant unit by stimulating innovation in mind-body and health research and/or fostering the development of junior scientists.
- o Appropriateness to the size and characteristics of the applicant institution's existing research program and the central scientific objectives and themes of the program.
- o Qualifications, experience, and commitment to the program of the investigators responsible for the activities and their ability to devote the required time and effort to the program.
- o Cost-effectiveness of services or activities and appropriateness of cost-sharing arrangements with the institution, relevant departments, and other external infrastructure support programs.
- o For pilot research programs, the appropriateness and quality of procedures and policies for administering the program, such as guidelines for reviewing applications, priorities for allocating funds, requirements for leveraging funds, and size and length of awards, and the quality for the projects selected for implementation in the first year.

3. Consortia:

Applications proposing to undertake any infrastructure activity in cooperation with another institution will be evaluated for the value added by the involvement of other institutions and the appropriateness and adequacy of plans for the sharing of rights and responsibilities among proposed partners with respect to the funding, administration, and use of shared resources.

C. ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

- o PROTECTIONS: The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

- o INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

- o BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: June 16, 2003

Application Receipt Date: July 16, 2003

Peer Review Date: October/November 2003

Council Review: January/February 2004

Earliest Anticipated Start Date: April 2004

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

- o Scientific merit (as determined by peer review)
- o Availability of funds
- o Programmatic priorities.

REQUIRED FEDERAL CITATIONS

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10

[_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10). The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES:

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority

areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance No. 93.989 (FIC), 93.213 (NCCAM), 93.395 and 93.393 (NCI), 93.867 (NEI), 93.837 (NHLBI), 93.866 (NIA), 93.273 (NIAAA), 93.856 (NIAID), 93.846 (NIAMS), 93.279 (NIDA), 93.121 (NIDCR), 93.848 (NIDDK), 93.242 (NIMH), and 93.853 (NINDS). This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at <http://grants.nih.gov/grants/policy/policy.htm> and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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